

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA,

Plaintiff,

v.

BAYER CORPORATION

Defendant.

Case No. 2:07-cv-00001
(Hon. Jose L. Linares)

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**DEFENDANT'S BRIEF IN SUPPORT OF ITS MOTION TO EXCLUDE
THE TESTIMONY OF DR. LOREN LAINE**

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INTRODUCTION

Defendant's motion to exclude Dr. Loren Laine's testimony is straightforward. This is a case about probiotics—specifically, the level of evidence needed to substantiate claims about probiotics. Dr. Laine admitted he is “not an expert in probiotics.” Laine Tr. 283:15-16¹; Laine Tr. 299:21-22 (“I am not an expert in probiotics, nor did I claim to be.”); *see also* Laine Tr. 348: 12-14; Laine Tr. 381:3-382:21. He also admitted he did “not pay[] attention to the regulations or law” when he designed his novel substantiation test. Laine Tr. 195:2-3. And his declarations, on their face, contradict one another. This Court should exclude his unreliable and unhelpful testimony.

BACKGROUND

The government seeks to subject Bayer to a novel substantiation standard for its probiotic supplement, Phillips' Colon Health (“PCH”). According to the government, Bayer needs to possess drug-level clinical trials—specifically, “human clinical trials that (1) are randomized, placebo-controlled, and double-blind; (2) use the specific product for which the claims are made; (3) are performed in the population at which the claims are directed; and (4) use validated methods and appropriate statistical methods to assess ‘outcomes’” (“Drug-Level RCTs”). *See* Dkt. No. 4-1 at 16.

¹ This citation format refers to the deposition transcript of Dr. Loren Laine, taken on December 14, 2014. The transcript is included as Exhibit A to the Certification of Timothy Duffy in Support of Bayer's Motion to Exclude the Testimony of Dr. Loren Laine.

In the government's contempt motion, the only asserted basis for this novel standard was Dr. Laine.² According to the government, to determine the appropriate amount of substantiation, the Court must look to what "experts in the field demand." Dkt. No. 38 at 3. The government asserted that Dr. Laine was the relevant expert.

In his deposition, however, Dr. Laine repeatedly admitted he is *not* a probiotics expert. Laine Tr. 283:15-16; *see also* Laine Tr. 299:21-22; Laine Tr. 348:12-14; Laine Tr. 381:3-382:21. He has never conducted a single "clinical trial" or "any study of any kind on probiotics." Laine Tr. 381:3-22. Nor has he ever written any "article," "books," or "clinical guidelines" on probiotics. *Id.*

Dr. Laine also admitted that he did "not pay[] attention to the regulations or law" when he designed his novel test, Laine Tr. 195:2-3, and made no effort to ensure that his test is consistent with the statutory or legal framework. Laine Tr. 183:20-184:3. Nor did he read, let alone consider, the FTC's Guidance on the proper level of substantiation for dietary supplements. Laine Tr. 197:2-4 ("Actually, the only time I saw [the FTC Guidance] was when you submitted it in your response."). Dr. Laine

² In its fifth brief, the government presented another purported expert, Dr. Frederic Bushman. In his declaration, he makes no mention of randomized, controlled clinical trials, and he has never designed such a trial. Bushman Tr. 78:20-22. Nonetheless, in his deposition, Dr. Bushman asserted he "agree[s] with Laine." Bushman Tr. 307:22. Because Dr. Bushman relies on Dr. Laine and admittedly is not an expert in either probiotic interventions or clinical trials, he provides no independent basis for the government's novel theory. *See also* Bayer's Motion to Exclude the Testimony of Dr. Frederic Bushman (filed concurrently with this motion).

treated the PCH dietary supplement *as a drug* and subjected it to the same clinical trial standard that is imposed on drugs. Laine Tr. 56:7-12.

ARGUMENT

District courts serve as the gatekeepers in ensuring the relevance and reliability of all expert testimony. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993); *see Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008). Federal Rule of Evidence 702 requires that (1) the proffered witness must be an expert; (2) the expert must testify to scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact. *See Voilas v. Gen. Motors Corp.*, 73 F. Supp. 2d 452, 455-56 (D.N.J. 1999); *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (The expert's conclusions must meet the "trilogy of restrictions on expert testimony: qualification, reliability and fit."). To be reliable under *Daubert*, an expert must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). An "expert's opinion . . . will aid the [trier of fact]" only "when there is a clear 'fit' connecting the issue in the case with the expert's opinion." *Meadows v. Anchor Longwall and Rebuild, Inc.* 306 Fed. Appx. 781, 790 (3d Cir. 2009).

This Court should exclude Dr. Laine's testimony for three reasons.

First, Dr. Laine is not an expert. This case is about probiotics, and Dr. Laine admittedly is "not an expert in probiotics." Laine Tr. 283:15-16; Laine Tr. 299:21-22. He has never conducted a single "clinical trial" or "any study of any kind on

probiotics.” Laine Tr. 381:3-22. Nor has he ever written any “article,” “books,” or “clinical guidelines” on probiotics. *Id.* Nor does he use them in his medical practice. Laine Tr. 271:2-10.

The government asserts, without explanation, that he is an “expert[] in the relevant area.” Dkt. No. 81 at 7; *see also id.* at 10 (“relevant experts”); *id.* at 11 (“experts in the relevant area”). What that “relevant area” is, the government never says. Originally, the government asserted that “gastroenterology” is the relevant area, but after Dr. Laine admitted that gastroenterologists do not require RCTs, *see* Laine Tr. 73:11-13; 79:12-19; 133:20-134:3; 140:17-141:6; 153:13-16; 158:15-20; 171:8-10, the government abandoned its position and now argues the practice of medicine is “irrelevant,” Dkt No. 84 at 15.

This case is about probiotics and the substantiation required for probiotic claims. Because Dr. Laine has no expertise in probiotics, Laine Tr. 283:15-16; Laine Tr. 299:21-22, the Court should “exclude [the] proffered expert testimony [which] . . . lies outside the witness’s area of expertise.” *In re: Diet Drugs*, 2001 WL 454586 at *15 (E.D.Pa. 2001) (collecting cases).

Second, Dr. Laine’s testimony cannot assist the trier of fact because it is inconsistent with federal law. Dr. Laine admitted he did “not pay[] attention to the regulations or law” when he designed his novel substantiation test, Laine Tr. 195:2-3, and he made no effort to reconcile his test with existing law, Laine Tr. 196:12-17; *see also In re Rezulin Prod. Liab.*, 309 F. Supp. 2d 531, 548-549 (S.D.N.Y. 2004) (excluding

testimony “evaluat[ing] [Defendant’s] conduct against FDA standards” when “the experts here in question disavow any expertise on the subject.”).

Dr. Laine’s position is that, regardless of federal law, there is only one way to substantiate claims: Drug-Level RCTs. According to Dr. Laine, Drug-Level RCTs should be required trials for *all* interventions—drugs, dietary supplements, foods, educational brochures—in *all* fields of study—rheumatology, ophthalmology, gastroenterology, physical therapy, and a variety of other fields. *See* Laine Tr. 127:16-132:10. He thinks his test should apply to “any situation.” Laine Tr. 55:2-7; *see also* Laine Tr. 127:22-128:7 (stating that RCTs are required “[f]or anything [...and] any intervention”); Laine Tr. 128:15-22 (claiming the test is not “unique to GIs”); Laine Tr. 128:21-22 (confirming that “this would be a general rule” and the standard is “not GI-based”); Laine Tr. 132:9-10 (stating that his test “is for interventions” and “[i]t doesn’t matter what the intervention is.”); Laine Tr. 499:4-21 (only exception to Dr. Laine’s test is for claims that simply say what the product is.); Second Dec. of Loren Laine at 9 (Dkt. No. 81-1) (“High-quality double-blind, placebo-controlled randomized clinical trials are well accepted as the appropriate method to yield accurate and reliable results for efficacy of a product, even for supplements.”). Dr. Laine was incredulous that anyone would suggest having different standards for different interventions. *See* Laine Tr. 131:2-7. He argued it is “illogical scientifically” to have a different meaning of “competent and reliable scientific evidence” “depending on the intervention being studied.” Second Dec. of Laine (Dkt. No. 81-1) at 15.

As Bayer and *amici* have explained, Dkt. Nos. 22, 24, 74, 84, 88, this one-size-fits-all theory conflicts with federal law. Dr. Laine’s position is facially inconsistent with the FTC Guidance and the terms of Bayer’s consent decree, which require only “competent and reliable scientific evidence.” FTC, *Dietary Supplements: An Advertising Guide for Industry* 3 (Apr. 2001), available at <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry/> (“FTC Guidance”); Dkt. No. 2 at 2. As the FTC Guidance makes clear, this is a “flexible” standard, which *does* differ depending on the intervention being studied. FTC Guidance at 3. The Guidance allows companies to look at the “totality of the evidence,” including animal and in vitro studies. *Id.* at 10, 14. The Guidance does not permit a rigid, across-the-board, Drug-Level RCT standard.

Dr. Laine’s position is also inconsistent with the Dietary Supplement Health & Education Act of 1994 (“DSHEA”), Pub. L. No. 103-417, 108 Stat. 4325, which holds dietary supplements to a different standard than drugs. Whereas new drugs must be supported by rigorous randomized, placebo-controlled, double-blind clinical trials, *see* 21 C.F.R. § 314.126, dietary supplements need not. Instead, dietary supplement claims must only be “truthful and not misleading.” 21 U.S.C. § 343(r)(6)(B); *see also id.* § 321(ff); *see also* Dkt. Nos. 22, 24, 84, 88. By eliding the distinction between drugs and dietary supplements, Dr. Laine conflicts with DSHEA.

Third, Dr. Laine’s declarations contradict one another. In his initial declaration, [REDACTED] Laine

Dec. at 20 (emphasis added). He likewise questioned the relevancy [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]. In his supplemental declaration, however, Dr. Laine reverses himself entirely. [REDACTED]

[REDACTED] One expert cannot have it both ways. [REDACTED]

[REDACTED] His testimony is not helpful to the trier of fact.

CONCLUSION

Dr. Laine is not an expert, his testimony is divorced from law, and he contradicts himself to suit the occasion. His testimony should be excluded.

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